Dartmouth-Hitchcock Medical Center

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August 28, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 98N-0607
Proposed Rule: General Requirements for Blood...Notification of Donors
21CFR Parts 606 and 630
August 19, 1999

Dear Sirs:

I am writing to request a change in provisions of the proposed rule with respect to its implications regarding the frequency and nature of communicating a deferral to a donor.

I fully support the concepts of requiring confirmatory testing and promptly notifying donors of deferrals. While I believe that most all blood collection agencies incorporate these elements into their standard operating procedures currently, including them in the CFR provides assurance to all donors.

Several aspects of the proposed rule, however, create unnecessary or burdensome requirements.

Notification attempts: There is no need to attempt to notify a donor three times. Most notifications will occur within days of the donation or, at most, several weeks later. If the donor is not to be found at the address that was given at the time of donation after this short interval, the address that was recorded was, in all probability, in error. Repeated attempts at notification will be equally fruitless. The blood collection agency should be expected to make a good faith effort to notify a deferred donor. This might include double checking an address in the record or verifying it against a phone book entry if a letter were returned as undeliverable. Such measures need not be codified, however.

Documentation of notification: The language of the proposed rule will force blood collection agencies to obtain certification that the deferred donor has received the deferral message. This, in essence, means sending all deferral notifications by certified mail, return receipt requested. Beyond the additional time and expense required, this step may have an undesired and undesirable psychological effect on the donor. It will greatly add to the perceived "weight" of the notification's message and may provoke unnecessary psychological stress if not prompt imprudent actions. The presence of a copy of the notification letter in the donor's file and the lack of its return by the Postal Service should be adequate documentation that the message was delivered.

98N-0607 C1

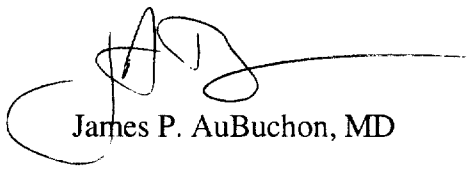
Comment: In making these suggestions, distinction is made between the situation of lookback-type recipient notifications and donor deferral notifications. In lookback, the recipient is utterly unaware of and is totally not responsible for the potential transmission of an infectious agent (probably) years earlier; multiple, diligent attempts at notification seem warranted in this situation. In the case of donors, the blood collecting agency is clearly not responsible for transmission of the infection and, in the past, has transmitted notification of the infection in the spirit of public health and medical responsibility. Placing the same type of diligence and documentation requirements on donor notification as is found in lookback situations is an inappropriate extension of logic and treads toward FDA regulation of the practice of medicine.

A parallel may be drawn from the private practice of medicine. If a patient has a test result that requires followup, the physician will attempt to notify the patient, either by telephone or in writing. However, I know of no physicians who would send the letter by certified mail, return receipt requested, or make three attempts to the only available address for the patient. Requiring such measures from a blood collecting agency places burdens on them that a physician's ethical code would not even require.

Therefore, I would request that the FDA simplify the regulations to require that the notification attempt be prompt and diligent and not specify further requirements.

Thank you.

Sincerely,



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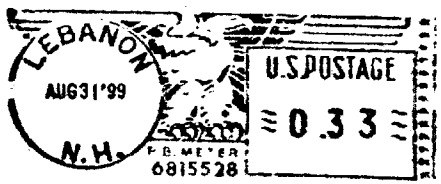

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